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K021245

510K Summary Statement for the de Gotzen "synchro" Intraoral Dental X-Ray System.

General Information

Manufacturer: de Gotzen S.r.l
Via Roma 45
21057 OLIGIATE OLONA (Varese) Italy

Establishment Registration:
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Contact Person: Antonella GASPARRI, International Compliance Office

Submitter: The Gotzen Group, Inc., (dba) TG Group, Inc. Canada
3505 Laird Road, Unit #7
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Establishment Registration: #9615032 & Health Canada Establishment: # 692
Telephone: (877) 557-4888 (Watts Line)
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Contact Person: Wayne Lebeau, President

USA Office: TG Group USA, LLC
30 Alden Terrace
Flanders, NJ 07836
Telephone: (973) 927-3730
Fax Line: (973) 927-4006
Contact Person: Donald R. Hill, VP Sales & Marketing
USA FDA Liaison

Summary Preparation Date: January 24, 2002

Name and Classification

Device Name: de Gotzen **synchro**
Intraoral Dental X-Ray System

Primary Classification Name: 90EHD – Unit, X-Ray, Extraoral with Timer

Classification Panel: Dental

Predicate Devices

The de Gotzen **synchro** Intraoral Dental x-ray System is substantially equivalent to the following previously cleared and currently marketed devices.

Aztech 70
Gendex Gx770
Sirona Heliodent Vario
Dent-x image X-70 Plus
Belmont Belray 096

Product Description

The de Gotzen **synchro** Intraoral Dental X-Ray System is comprised of the following main components:

- X-Ray tubehead and yoke
- Articulating arm
- Horizontal arm, standard length
- Wall Mount
- Electronic control timer (which may be mounted remotely)
- 8" and 12" Collimating cones

Optional components:

- Horizontal arm, short length
- Horizontal arm, long length
- Rectangular collimating cone

The power supply (Timer) is regulated to provide a fixed 70kVp, and the x-ray target current is fixed at 8ma. Predefined exposure times may be selected directly through the control timer switchpads. The range of exposure time is 0.08 through 3.2 seconds

Intended Use:

The de Gotzen **synchro** Intraoral Dental X-Ray System is an Extraoral source of x-rays for Intraoral images in dental radiography.

Comparison of Technological Characteristics:

Rationale for Substantial Equivalence.

The de Gotzen **synchro** Intraoral Dental X-Ray System shares the same indications for use, similar materials, design, operational, and functional features and therefore is Substantially Equivalent to the predicate devices listed in this summary.

Table comparing performance of de Gotzen synchro with predicate devices:

Specifications	Aztech 70	Gendex Gx770	Sirona Heliodent Vario	Dent-x Image x-70 Plus	Belmont Belray 096	de Gotzen synchro
Registration Number	K984524	K935046	K000672	K000551	K963699	
Line Requirements	110V-120V 50Hz - 60Hz	110V - 130V 60Hz	100V/110V/120V, 11A 220V/230V/240V, 6A 50Hz/60Hz	110V/220V, 50Hz/60Hz	108V - 132V 50Hz.60Hz	220V/230V/240V, 8A 110V -120V 5.5A 50hZ - 60hZ
Generator Type	AC	AC	AC Single Pulse	AC	AC	AC
Tube Voltage	65 kV	70 kV	70 kV	70 kV	70 kV	70 kV
Tube Current	8 mA	7 mA	7mA	8 mA	10 mA	8 mA
Exposure Time Selection	0.03 -3.0 Sec	3-99 impulses (28 Steps)	0.03 - 3.2 Sec	0.08 -3.2 Sec	0.02 -3.0 Sec	0.08 - 3.2 Sec. 17 Steps
Focal Spot	0.7	0.6mm	0.8mm	0.7 X 0.7 mm	0.8 X 0.8mm	0.7 X 0.7mm
Focal Length	8in/12in	8in/12in	8in/12in	8in/12in	8in/12in	8in/12in
Total Filtration in X-ray tube unit	Unknown	Unknown	>2 mm Al	>2.5 mm Al	>2.1 mm Al	>2.0 mm Al
Leakage Radiation	Unknown	Unknown	0.25 mGy/h (0.25 mA/70kV)	28 mR/hr at 1m from focal spot	Unknown	Less than 2.5 mGy/h
Compatiabel with Film and Digital	Yes	Yes	Yes	Yes	Yes	Yes

Conclusion

The deGotzen synchro Intraoral Dental X-Ray System was found to be /is substantially Equivalent to the predicate devices; the Aztech 70, Gendex Gx770, Siron Heliodent Vario, Dent-x image x-70, and Belmont Belray 096. The de Gotzen **synchro** shares the same indications for use, similar materials, design, operational, and functional features as the current marketed predicate devices. It has been shown to be safe and effective when used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

The Gotzen Group, Inc.
% Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K021245
Trade/Device Name: deGotzen synchro
Intraoral X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: April 18, 2002
Received: April 19, 2002

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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XI. INDICATIONS FOR USE STATEMENT

Applicant: de Gotzen S.r.L.

510(k) Number (if known): k 021245

Device Name: de Gotzen "synchro" Intraoral Dental X-Ray System

Indications for Use: The de Gotzen "synchro" Intraoral Dental X-Ray System is an Extraoral Source X-Ray System, intended to be used for dental radiographic examinations and diagnosis of the teeth, jaw, and oral structures.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021245

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT
And Radiological Devices

510K Number_____